

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA**

IVERA MEDICAL CORPORATION,  
Plaintiff,

vs.

EXCELSIOR MEDICAL  
CORPORATION,  
Defendant.

IVERA MEDICAL CORPORATION,  
Plaintiff,

vs.

HOSPIRA, INC.,  
Defendant.

IVERA MEDICAL CORPORATION,  
Plaintiff,

Case Nos.:  
11-cv-1115-H-RBB  
11-cv-1246-H-RBB  
12-cv-954-H-RBB  
12-cv-1581-H-RBB  
12-cv-1582-H-RBB  
12-cv-1587-H-RBB

**ORDER:**

**1) GRANTING DEFENDANTS'  
MOTIONS FOR SUMMARY  
JUDGMENT OF PATENT  
INVALIDITY;**

[1115] Doc. Nos. 73 & 87  
[1246] Doc. No. 136

**and**

**2) DENYING PLAINTIFF'S  
MOTIONS FOR SUMMARY  
JUDGMENT;**

[1115] Doc. No. 71  
[1246] Doc. No. 133  
[954] Doc. No. 82

1 vs.  
2 CATHETER CONNECTIONS, INC.,  
3  
4 Defendant.

5 These actions involve six consolidated patent infringement actions brought by  
6 Plaintiff against Defendants for infringing U.S. Patent Nos. 7,780,794 (“the ’794  
7 patent”), 7,985,302 (“the ’302 patent”), and 8,206,514 (“the ’514 patent”) (collectively,  
8 the “patents-in-suit”). The ’302 and ’514 patents are continuations of the ’794 patent,  
9 and contain the same specification. The Court consolidated the Catheter Connections  
10 actions, Case Nos. 12-cv-954-H and 12-cv-1587-H, on February 8, 2013. ([954]<sup>1</sup> Doc.  
11 No. 32.) The Court consolidated the Excelsior actions, Case Nos. 11-cv-1115-H and  
12 12-cv-1581-H, on February 26, 2013. ([1115]<sup>2</sup> Doc. No. 37.) The Court consolidated  
13 the Hospira actions, Case Nos. 12-cv-1246-H and 12-cv-1582-H, on March 7, 2013.  
14 ([1246]<sup>3</sup> Doc. No. 37.)

15 On April 4, 2014, Plaintiff Ivera Medical Corporation filed a motion for  
16 summary judgment in each consolidated action, and Defendants Excelsior Medical  
17 Corporation and Hospira, Inc. filed cross-motions for summary judgment, including a  
18 motion for patent invalidity. ([1115] Doc. Nos. 71 & 73; [1246] Doc. Nos. 133 & 136;  
19 [954] Doc. No. 82.) On April 18, 2014, Defendants Excelsior,<sup>4</sup> Hospira, and Catheter  
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24 <sup>1</sup> “[954]” refers to Ivera Medical Corporation v. Excelsior Medical Corporation,  
No. 12-cv-954-H.

25 <sup>2</sup> “[1115]” refers to Ivera Medical Corporation v. Excelsior Medical Corporation,  
26 No. 11-cv-1115-H.

27 <sup>3</sup> “[1246]” refers to Ivera Medical Corporation v. Excelsior Medical Corporation,  
No. 11-cv-1246-H.

28 <sup>4</sup>Excelsior lodged its opposition under seal. (See [1115] Doc. No. 98.)

1 Connections, Inc. filed their responses in opposition to Ivera's motions.<sup>5</sup> ([1115] Doc.  
2 No. 90; [1246] Doc. No. 146; [954] Doc. No. 93.) On April 21, 2014, the Court issued  
3 an order stating that it would address the issue of patent invalidity in all of the  
4 consolidated actions. ([954] Doc. No. 94.) On April 23, 2014, each party filed a reply.  
5 ([1115] Doc. Nos. 104 & 105; [1246] Doc. No. 151; [954] Doc. No. 95.)

6 The Court held a hearing on Tuesday, April 29, 2014. Jonathan Hangartner  
7 appeared on behalf of Ivera. John E. Flaherty, Mark Anania, and Michael Murphy  
8 appeared on behalf of Excelsior. Daniel A. Boehen, Joshua Reuben Rich, and Timothy  
9 R. Pestotnik appeared on behalf of Hospira. Edward F. O'Connor and Vicki E. Farrar  
10 appeared on behalf of Catheter Connections. The Court grants Defendants' motions  
11 for summary judgment of patent invalidity, denies Plaintiff's motions for summary  
12 judgment, and denies all other motions as moot.

### 13 **Background**

14 The invention concerns devices for decontaminating medical implements, where  
15 the prototypical device is placed as a cap over the part of the medical implement (or  
16 "site") to be cleaned, swabbing the site with a cleaning agent pre-loaded into the  
17 device. See, e.g. '794 Patent, Abstract. Defendants' answers assert invalidity and non-  
18 infringement counterclaims, among other responses. ([1115] Doc. No. 24; [1246] Doc.  
19 No. 55; Doc. No. 14.)

20 Ivera asserts that Excelsior's SwabCap products, Hospira's LifeShield Effect-IV  
21 Cap products, and Catheter Connections's DualCap Solo products infringe some or all  
22 of the following patent claims: independent claims 12, 13, and 20 of the '794 Patent  
23 (in addition to dependent claims 15, 16, 18, and 21); independent claims 1, 7, 13, and  
24 18 of the '302 Patent (in addition to dependent claims 2-6, 8-12, 14-17, and 19-21); and  
25 independent claims 1, 11, and 21 of the '514 Patent (in addition to dependent claims  
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27 <sup>5</sup>Ivera filed its corrected oppositions to Defendants Excelsior's and Hospira's  
28 motions for summary judgment on April 23, 2014. ([1115] Doc. No. 100; [1246] Doc.  
No. 149.)

2-8, 12-18, 20, 22-25, and 27). (See Plaintiff’s Amd. Infr. Contentions, [1115] Doc. No. 71-3; [1246] Doc. No. 133-3; and [953] Doc. No. 82-3.) On October 2, 2013, the Court issued its Markman order construing the disputed claim terms. ([1115] Doc. No. 59.)

Excelsior petitioned the United States Patent and Trademark Office (“PTO”) for inter partes reexamination of the ’794, ’302, and ’514 patents on August 24, 2010, July 26, 2011, and June 26, 2012 respectively. ([1115] Doc. Nos. 47-20, 47-16, and 47-23.) On November 2, 2012, the Patent Office issued three office actions; the first invalidated claims 12-18, 20-21, and 23-24 of the ’794 patent; the second invalidated claims 1-25 of the ’302 patent; and the third invalidated claims 1-37 of the ’514 patent. ([1115] Doc. Nos. 47-22, 47-18, and 47-26.) The Patent Office issued actions closing prosecution (ACPs) confirming the decisions on May 10, May 14, and May 14, 2013. ([1115] Doc. Nos. 45-23, 45-19, and 45-27.) On April 4, 2014, the PTO issued Right of Appeal Notices in the inter partes reexaminations for each of the patents-in-suit declaring all asserted claims to be invalid. ([1115] Doc. No. 81.)

Defendants move for summary judgment on the grounds that the asserted claims of the patents-in-suit are invalid due to anticipation and obviousness. (See [1115] Doc. No. 73; [1246] Doc. No. 136; see also [954] Doc. No. 94.) Defendants also move for summary judgment on the grounds that their products do not infringe the patents-in-suit. (Id.) Plaintiff opposes and moves for summary judgment of infringement. ([1115] Doc. Nos. 71 & 100; [1246] Doc. No. 133 & 149.)

## **Discussion**

### **I. Legal Standard for Summary Judgment**

Summary judgment is appropriate under Rule 56 of the Federal Rules of Civil Procedure if the moving party demonstrates the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A fact is material when, under the governing substantive law, it could affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248

1 (1986); Nat'l Ass'n of Optometrists & Opticians v. Harris, 682 F.3d 1144, 1147 (9th  
2 Cir. 2012) cert. denied, 133 S. Ct. 1241 (2013). A dispute is genuine if a reasonable  
3 jury could return a verdict for the nonmoving party. Anderson, 477 U.S. at 248.

4 A party seeking summary judgment bears the initial burden of establishing the  
5 absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. The moving  
6 party can satisfy this burden in two ways: (1) by presenting evidence that negates an  
7 essential element of the nonmoving party's case; or (2) by demonstrating that the  
8 nonmoving party failed to establish an essential element of the nonmoving party's case  
9 on which the nonmoving party bears the burden of proving at trial. Id. at 322-23.  
10 "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary  
11 judgment." T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n, 809 F.2d 626,  
12 630 (9th Cir. 1987). Once the moving party establishes the absence of genuine issues  
13 of material fact, the burden shifts to the nonmoving party to set forth facts showing that  
14 a genuine issue of disputed fact remains. Celotex, 477 U.S. at 322. The nonmoving  
15 party cannot oppose a properly supported summary judgment motion by "rest[ing] on  
16 mere allegations or denials of his pleadings." Anderson, 477 U.S. at 256. "The  
17 'opponent must do more than simply show that there is some metaphysical doubt as to  
18 the material fact.'" Kennedy v. Allied Mut. Ins. Co., 952 F.2d 262, 265-66 (9th Cir.  
19 1991) (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586  
20 (1986)).

21 When ruling on a summary judgment motion, the district court must view all  
22 inferences drawn from the underlying facts in the light most favorable to the  
23 nonmoving party. Matsushita, 475 U.S. at 587. The district court does not make  
24 credibility determinations with respect to evidence offered. See T.W. Elec., 809 F.2d  
25 at 630-31 (citing Matsushita, 475 U.S. at 587). Summary judgment is therefore not  
26 appropriate "where contradictory inferences may reasonably be drawn from undisputed  
27 evidentiary facts." Hollingsworth Solderless Terminal Co. v. Turley, 622 F.2d 1324,  
28 1335 (9th Cir. 1980).

## 1 II. Legal Standards for Obviousness

2 A claimed invention is obvious if “the differences between the subject matter  
3 sought to be patented and the prior art are such that the subject matter as a whole would  
4 have been obvious at the time the invention was made to a person having ordinary skill  
5 in the art.” 35 U.S.C. § 103(a). Obviousness is a legal question based on underlying  
6 factual determinations. Eisai Co. Ltd. v. Dr. Reddy’s Lab., Ltd., 533 F.3d 1353, 1356  
7 (Fed. Cir. 2008). “The factual determinations underpinning the legal conclusion of  
8 obviousness include 1) the scope and content of the prior art, 2) the level of ordinary  
9 skill in the art, 3) the differences between the claimed invention and the prior art, and  
10 4) evidence of secondary factors.” Id. (citing Graham v. John Deere Co., 383 U.S. 1,  
11 17-18 (1966)). Secondary factors include “commercial success, long felt but unsolved  
12 needs, failure of others, etc.” KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007)  
13 (quoting Graham, 353 U.S. at 17-18.) A patent issued by the PTO is presumed to be  
14 valid. Microsoft Corp. v. i4i Ltd. P’ship, 131 S.Ct. 2238, 2242 (2011). In order to  
15 overcome the presumption of validity, a party must prove invalidity by clear and  
16 convincing evidence. Id. But summary judgment may be appropriate if “the content  
17 of the prior art, the scope of the patent claim, and the level of ordinary skill in the art  
18 are not in material dispute, and the obviousness of the claim is apparent.” KSR Int’l  
19 Co. at 427.

20 A patent is likely to be obvious if it merely yields predictable results by  
21 combining familiar elements according to known methods. Id. at 416. “[A] patent  
22 composed of several elements is not proved obvious merely by demonstrating that each  
23 of its elements was, independently, known in the prior art.” Id. at 418. “If a person of  
24 ordinary skill in the art can implement a predictable variation, and would see the  
25 benefit of doing so, § 103 likely bars its patentability.” Id. at 417. In determining  
26 obviousness, courts do not need to find “precise teachings directed to the specific  
27 subject matter of the challenged claim, for a court can take account of the inferences  
28 and creative steps that a person of ordinary skill in the art would employ.” Id. at 418.

1 A person of ordinary skill interprets the prior art “using common sense and appropriate  
 2 perspective.” Unigene Labs., Inc. v. Apotex, Inc., 655 F.3d 1352, 1361 (Fed. Cir.  
 3 2011) (citing KSR Int’l Co., 550 U.S. at 421). As the Supreme Court observed:

4 When there is a design need or market pressure to solve a problem and  
 5 there are a finite number of identified, predictable solutions, a person of  
 6 ordinary skill has good reason to pursue the known options within his or  
 her technical grasp. If this leads to the anticipated success, it is likely the  
 product not of innovation but of ordinary skill and common sense.

7 KSR Int’l Co., 550 U.S. at 421. The results of ordinary innovation are not patentable.  
 8 Id. at 427. Furthermore, “when a patent ‘simply arranges old elements with each  
 9 performing the same function it had been known to perform’ and yields no more than  
 10 one would expect from such an arrangement, the combination is obvious.” KSR Int’l  
 11 Co., 550 U.S. at 417 (quoting Sakraida v. AG Pro, Inc., 425 U.S. 273 (1976)).

### 12 **III. Analysis**

#### 13 **1. Scope and Content of Prior Art**

14 Under the first element of the Graham test for obviousness, the Court determines  
 15 the scope and content of the prior art. Graham, 383 U.S. at 17. At least three prior art  
 16 references are relevant to the patents-in-suit: Hoang, Chin-Loy, and White. See U.S.  
 17 Patent App. Pub. No. 2007/0112332; U.S. Patent No. 5,954,957; U.S. Patent No.  
 18 5,242,425. All predate the earliest application date of the patents-in-suit, and are from  
 19 the same field of endeavor, namely, the decontamination of medical devices. See In  
 20 re Clay, 966 F.2d 656, 659 (Fed. Cir. 1992) (holding that when “the art is from the  
 21 same field of endeavor,” it is analogous for a court’s obviousness inquiry). The Court  
 22 describes each in turn:

##### 23 **a. Hoang**

24 U.S. Patent Application Publication No. 2007/0112333 to Hoang et al.  
 25 (“Hoang”) teaches an antiseptic cap for sterile cleaning and maintaining patient line  
 26 access vales (such as a luer valve) to reduce microbes on the valve’s access portion.  
 27 See Hoang, Brief Summary of the Invention. The cap includes a hood containing a pad  
 28 impregnated with an antimicrobial agent, and it covers the valve’s access portion when



1 the valve is not in use. Id., Abstract. The cap is designed to maintain an antiseptic  
2 environment and minimize the risk of infection from catheters that attach via the  
3 valves. Id. The design also discloses a foil seal to maintain the antimicrobial agent and  
4 provide a moisture barrier, as well as threads along the inside of the cap's opening to  
5 engage the valve. Id. ¶¶ 19-24.

6 b. Chin-Loy

7 U.S. Patent No. 5,954,957 ("Chin-Loy,") discloses a cap that can be attached to  
8 certain hydraulic fitting ports of certain medical devices. U.S. Patent No. 5,954,957,  
9 Abstract. The medical devices are used for purifying and concentrating biological  
10 liquids, such as in blood dialysis. Id. col.1 ll.8-11. Chin-Loy discloses that the medical  
11 devices are normally sold in a sterile condition, with disposable caps that cover the  
12 device's ports until it can be used. Id. col.1 ll.39-42. The patent teaches an  
13 embodiment of the cap that includes a channel such that the cap may be fully attached  
14 but also permit venting of the medical device through the port while maintaining the  
15 internal sterile condition of the medical device until time of use. Id. col.2 ll.38-44.  
16 Chin-Loy discloses a preferred embodiment wherein the cap attaches to a blood port  
17 with the male part configured as an enlarged luer taper surrounded by a female threaded  
18 collar. Id. col.4 ll.23-30 & 50-57. Chin-Loy also discloses a channel formed when the  
19 cap is fully attached to a blood port of a medical device and "permits venting of the  
20 interior of the medical device through the blood port during sterilization of the medical  
21 device." Id. col.5 ll.1-20.

22 c. White

23 U.S. Patent No. 5,242,425 ("White") discloses an antiseptic catheter assembly  
24 formed by an interconnection of male (tubular) and female (luer) members coupled to  
25 a self-sealing sanctum, as well as an outer protective cap that covers the coupling to  
26 maintain an antiseptic condition. U.S. Patent No. 5,242,425, col.2 ll.53-64. According  
27 to a preferred embodiment, the outer cap houses an absorbent material saturated with  
28 an antiseptic that contacts the coupling when the protective cap is engaged. Id. White



1 teaches an embodiment where the cap is spaced from the coupled assembly, forming  
 2 a cavity that allows the “exterior surfaces” of the connector to be bathed with antiseptic  
 3 when the cap is in place. Id. col.7 ll.23-35. The cap is provided with threads that  
 4 engage threads on the connector to create a re-sealable connection. See id. Fig. 7; id.  
 5 col.7 ll.36-38. White teaches that while the coupling requires “a very tight fit . . . so  
 6 that the so that the two members are in a fluid tight relationship for low pressures,” id.  
 7 col.6 ll.40-48, the cap containing the antiseptic material “is sized to be slip-fit . . . and  
 8 rests on [the] border rim or ledge” of the coupling, id. col.6 ll.9-15.

## 9           **2.       The Level of Ordinary Skill in the Art**

10           The second element in the Graham test for obviousness requires the Court to  
 11 determine the level of ordinary skill in the pertinent art. See Graham, 383 U.S. at 17-18.  
 12 “The importance of resolving the level of ordinary skill in the art lies in the necessity  
 13 of maintaining objectivity in the obviousness inquiry.” Ryko Mfg. Co. v. Nu-Star, Inc.,  
 14 950 F.2d 714, 718 (Fed. Cir. 1991). Factors to consider include the educational level  
 15 of the inventor, the educational level of those who work in the relevant industry, and  
 16 the sophistication of the technology involved. See id.

17           The parties’ invalidity experts do not depart materially from one another in their  
 18 proffered definitions of one having ordinary skill in the art. Defendant Excelsior’s  
 19 expert, Charles Clemens, concluded that a person of ordinary skill in the art “has at  
 20 least a bachelor’s degree in mechanical engineering, biomedical engineering, or a  
 21 comparable field and at least 5-7 years of training and experience, or additional  
 22 schooling in medical device design, including experience associated with ‘single use’  
 23 disposable administration set design.” ([1115] Doc. No. 87-1, Ex. A, Clemens Report.)  
 24 Defendant Hospira’s expert, Neil J. Sheehan, opined that “one of ordinary skill in the  
 25 art would have a mechanical engineering, biomedical engineering, or similar technical  
 26 degree or equivalent work experience, and five to ten years of technical (design or  
 27 development) work in the field.” ([1246] Doc. No. 136-10, Ex. G, Sheehan Report.)  
 28 Ivera’s expert, Karl R. Leinsing, concluded that a person of ordinary skill in the art has

1 “a B.S. in mechanical engineering or equivalent education and training and at least one  
 2 to two years of experience in the medical device industry,” but allowed that accepting  
 3 Defendants’ experts definitions would not change his opinions. ([1115] Doc. No. 94-1  
 4 at 16; [1246] Doc. No. 148-1 at 16.) The Court recognizes the level of ordinary skill  
 5 in the art to be a person with a bachelor’s degree in mechanical engineering, biomedical  
 6 engineering, or a comparable field with anywhere from two to five years’ work  
 7 experience in the disposable medical device industry.

### 8 **3. Differences Between the Prior Art and the Claimed Inventions**

9 The next Graham element analyses requires the Court to determine whether there  
 10 are material differences between the teachings found in the prior art and the claimed  
 11 invention, from the vantage point of a hypothetical person with ordinary skill in the art.  
 12 Graham, 383 U.S. at 17-18. “It is elementary that the claimed invention must be  
 13 considered as a whole in deciding the question of obviousness.” Litton Indus. Prods.  
 14 v. Solid State Sys. Corp., 755 F.2d 158, 164 (Fed. Cir. 1985)

15 The patents-in-suit share the same specification and broadly disclose a cleaning  
 16 device for medical implements. Compare ’794 Patent, ’302 Patent, and ’514 Patent.  
 17 The invention includes a cap with an inner cavity and an opening to that cavity which  
 18 is adapted to receive the medical implement. Id. The patents disclose a compressible  
 19 cleaning material, pre-loaded with a cleaning agent, within the cavity before it receives  
 20 the site of the medical implement to be sterilized. Id., col.2 ll.15-26. Similarly, the  
 21 relevant prior art discloses similar elements.

22 “When a patent ‘simply arranges old elements with each performing the same  
 23 function it had been known to perform’ and yields no more than one would expect from  
 24 such an arrangement, the combination is obvious.” KSR Int’l Co., 550 U.S. at 417  
 25 (quoting Sakraida v. AG Pro, Inc., 425 U.S. 273 (1976)). Here, the patents-in-suit  
 26 contain the same elements that perform the same functions they had been known to  
 27 perform in the prior art. For example, Claim 13 of the ’794 Patent provides for:

28 ///

1 A cleaning device for a medical implement, the cleaning device  
comprising:

2 a cap having a first opening to an inner cavity, an inner surface of  
the first opening including one or more threads adapted to receive a site  
3 of the medical implement;

4 a cleaning material formed of a compressible material that is at least  
partially secured in the inner cavity, the cleaning material containing a  
cleaning agent;

5 a second opening in the cap to allow evaporation of the cleaning  
agent from the inner cavity and to inhibit a buildup of pressure in the cap  
6 when the cleaning material is compressed by the site of the medical  
implement and a removable covering that covers the first opening and the  
7 second opening to the inner cavity prior to coupling the threads of the cap  
with the site of the medical implement via the first opening.

8  
9 ('794 Patent, col.10 ll.1-17.) Claim 1 of the '302 Patent provides for:

10 A cleaning device for a medical implement, the cleaning  
device comprising:

11 a cap having an opening to an inner cavity, the opening for  
receiving a site of the medical implement;

12 threading at least partially around an inside surface of the cap  
near a periphery of the opening to the inner cavity, the threading to  
engage corresponding threads on the site of the medical implement;

13 a compressible cleaning material in the inner cavity and  
containing a cleaning agent, the compressible cleaning material  
14 adapted to swab and clean the site with the cleaning agent;

15 at least one aperture to the inner cavity to allow venting from  
the inner cavity when the opening receives the site of the medical  
implement; and

16 a removable seal attached to the cap at the opening to cover  
the opening and to maintain the compressible cleaning material and  
17 cleaning agent within the inner cavity prior to receipt of the site of  
the medical implement.

18  
19 ('302 Patent, col.8 ll.50 - col.9 l.2.) Additionally, Claim 1 of the '514 Patent provides  
20 for:

21 A cleaning device for a medical implement, the cleaning device  
comprising:

22 a cap having an opening to an inner cavity, the opening for  
receiving a site of the medical implement;

23 one or more protrusions extending inwardly at least partially around  
an inside surface of the cap near a periphery of the opening to the inner  
cavity, the one or more protrusions to engage an outer surface of the site  
24 of the medical implement to maintain the cap on the site of the medical  
implement;

25 a cleaning agent that occupies at least some of the inner cavity, the  
cleaning agent being formulated to clean the site when the opening of the  
cap receives the site of the medical implement;

26 at least one aperture to the inner cavity to allow venting from the  
inner cavity when the opening of the cap receives the site of the medical  
27 implement; and

28 a removable seal that covers the opening to maintain the cleaning

1 agent within the inner cavity prior to receipt of the site of the medical  
2 implement.

3 ('514 Patent, col.8 l.54 - col.9 l.6.) These representative claims teach a first opening  
4 for receiving the medical implement, in addition to a second opening or aperture to  
5 allow venting or evaporation from the inner cavity. The Court's October 2, 2013 claim  
6 construction construed the meaning of "second opening" as "a second, distinct channel  
7 or pathway that extends from the interior to the exterior of the cap."<sup>6</sup> ([1115] Doc. No.  
8 59.) In the final analysis, the invention as a whole claims a disinfecting cap with a foil  
9 seal pre-loaded with cleaning agent having a first opening that receives the medical  
10 implement to be cleaned, and a second opening or aperture to allow venting.

11 Comparing the claimed invention to the prior art, the arrangement of elements  
12 in the asserted claims do not yield anything other than predictable results. Plaintiff's  
13 validity expert admitted that such a result would not be unexpected to a person of  
14 ordinary skill in the art. (See [1115] Doc. No. 94-1 Leinsing Report ("In my opinion  
15 it was predictable that caps practicing the claimed invention reduce somewhat the  
16 incidence of bloodstream infections.")) Defendants contend that it would be obvious  
17 to a person of ordinary skill in the art to combine Hoang with the benefits provided by  
18 the second openings or apertures found in Chin-Loy and White. "Common sense  
19 teaches . . . that familiar items may have obvious uses beyond their primary purposes,  
20 and in many cases a person of ordinary skill will be able to fit the teachings of multiple  
21 patents together like pieces of a puzzle." KSR Int'l Co., 550 U.S. at 420.

22 ///

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24  
25 <sup>6</sup> Other asserted claims have additional limitations. For instance, certain claims  
26 require a seal to cover both the device's first opening and its second opening or  
27 aperture, (e.g., '794 Patent Claims 12, 13, 15, 18, 20 and 21; '302 Patent Claims 7-12  
28 & 18-21), whereas other claims require the seal to cover the device's first opening and  
not necessarily a second opening or aperture, (e.g., '514 Patent Claims 1-8, 11-18, and  
21-25; '302 Patent Claims 1-6). The Court incorporates by reference its analysis of the  
asserted claims in its order denying Defendant Catheter Connection's motion for  
summary judgment of non-infringement. ([954] Doc. No. 78.)

1 A patent that is merely a combination of familiar elements, when combined using  
2 known methods that produces predictable results, is likely obvious. KSR Int’l Co., 550  
3 U.S. at 418. The inquiry is whether, to a person of ordinary skill in the art, it would be  
4 obvious to modify Hoang to create a device with a second opening or aperture that  
5 vented cleaning agent. See Smith & Nephew, Inc. v. Rea, 721 F.3d 1371, 1380-81  
6 (Fed. Cir. 2013) (citing KSR Int’l Co., 550 U.S. at 417). The Court notes little  
7 difference between the subject matter of the patents-in-suit and the Hoang reference,  
8 except that Hoang does not explicitly disclose a second opening or aperture that allows  
9 the device to vent the cleaning agent.<sup>7</sup>

10 Here, modifying Hoang to add a second opening or aperture would yield  
11 predictable results: it would allow the cleaning agent to vent after the cap placed on the  
12 luer valve. A person of ordinary skill in the art would not need the benefit of hindsight  
13 to realize that adding a vent would relieve possible pressure on the inside of the cap.  
14 One having ordinary skill in the art would also see the benefit that the Chin-Loy  
15 patentees saw: that having a channel formed when the cap is fully attached “permits  
16 venting of the interior of the medical device through the blood port during sterilization  
17 of the medical device.” Chin-Loy, col.5 ll.1-20. In addition, such a change would  
18 allow the cleaning agent to vent onto the exterior of the medical implement, sterilizing  
19 a larger portion of it. This benefit was expressly observed in White, teaching an  
20 alternative embodiment where the outer cap, containing a sponge soaked with  
21 antiseptic, “is spaced from proximal member or injection cap 82 to permit antiseptic  
22 to bathe the exterior surfaces of distal member 70, proximal member 82, and  
23 self-sealing septum.” White, col.7 ll.23-35. “[I]f a technique has been used to improve  
24 one device, and a person of ordinary skill in the art would recognize that it would  
25 improve similar devices in the same way, using the technique is obvious unless its

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26  
27 <sup>7</sup> To the extent that Defendants Excelsior and Hospira move for summary  
28 judgment on the grounds that Hoang wholly anticipates the asserted claims under 35  
U.S.C. § 102, the Court denies their motions.

1 actual application is beyond his or her skill.” KSR Int’l Co., 550 U.S. at 417.

2 Obviousness is a question of law for the Court. KSR Int’l Co., 550 U.S. at 427.  
 3 Like the PTO’s conclusion of obviousness under its standards,<sup>8</sup> the Court concludes  
 4 that Hoang, in view of either Chin-Loy or White, renders the asserted claims invalid  
 5 for obviousness under Graham. Here, the differences between the subject sought to be  
 6 patented and the prior art are such that the subject matter as a whole would have been  
 7 obvious at the time that the invention was made to a person having ordinary skill in the  
 8 art. 35 U.S.C. § 103(a). Considering the prior art, the scope of the patent claims, and  
 9 the level of skill in the art, the record demonstrates no triable issue of material fact on  
 10 obviousness for the asserted claims of the patents-in-suit. See, e.g., Media Tech.  
 11 Licensing, LLC v. Upper Deck Co., 596 F.3d 1334, 1339 (Fed. Cir. 2010) (affirming  
 12 a district court’s summary judgment of obviousness on the grounds that, inter alia,  
 13 defendants met their burden to show that a person of ordinary skill would have  
 14 combined the prior art references).

#### 15 4. Secondary Considerations

16 Additionally, the record demonstrates no triable issue of material fact on  
 17 secondary factors of non-obviousness to rebut the conclusion that the asserted claims  
 18 of the patents-in-suit are obvious. Ivera’s oppositions to Defendants’ motions rest on  
 19 the expert reports of Mr. Leinsing and Mr. Kennedy in a conclusory fashion. ([1115]  
 20 Doc. No. 100 at 22; [1246] Doc. No. 147 at 29.) The reports present expert opinion  
 21 testimony that Ivera’s invention filled a long-felt but unmet need, yielded unexpected  
 22 results, and experienced commercial success, but even drawing all factual inferences

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24 <sup>8</sup> The Court takes judicial notice that all asserted claims have been rejected on  
 25 multiple grounds in Rights of Appeal Notices that the PTO issued in the inter partes  
 26 reexamination proceedings. ([1115] Doc. No. 81.) See Function Media, L.L.C. v.  
 27 Google Inc., 708 F.3d 1310, 1316 n.4 (Fed. Cir. 2013) (taking judicial notice of a PTO  
 28 action holding all asserted claims invalid on reexamination); Old Reliable Wholesale,  
Inc. v. Cornell Corp., 635 F.3d 539, 549 (Fed. Cir. 2011) (“Although the results of the  
 PTO reexamination proceedings were not available to the district court, this court can  
 take judicial notice [of them].”).



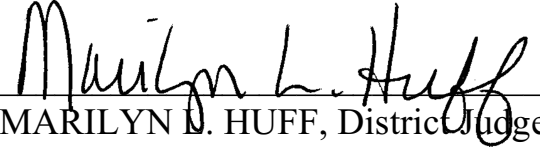
1 in Plaintiff's favor, it is not enough to present a triable issue of material fact on  
2 obviousness as a matter of law. "Where, as here, the content of the prior art, the scope  
3 of the patent claim, and the level of ordinary skill in the art are not in material dispute,  
4 and the obviousness of the claim is apparent in light of these factors, summary  
5 judgment is appropriate." KSR Int'l Co., 550 U.S. at 427. The asserted claims  
6 encompassed obvious subject matter regardless of evidence of secondary factors, and  
7 as a result fail to meet the requirement of § 103.

8 **Conclusion**

9 The Court grants Defendants' motions for summary judgment on the issue of  
10 validity and invalidates the asserted claims of the patents-in-suit for obviousness.  
11 Accordingly, the Court denies the pending motions as moot.<sup>9</sup>

12 **IT IS SO ORDERED.**

13 DATED: April 29, 2014

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15 MARILYN E. HUFF, District Judge  
16 UNITED STATES DISTRICT COURT  
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26 <sup>9</sup>The Court denies as moot Excelsior's motions to exclude expert testimony and  
27 to stay ([1115] Doc. Nos. 82 & 74); denies Hospira's motion to stay, motion in limine,  
28 and two motions to preclude expert testimony ([1246] Doc. Nos. 141 & 152-154); and  
denies Catheter Connections's motion to stay ([954] Doc. No. 87).